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No. 84-1032

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

ALCON LABORATORIES (PUERTO RICO), INC., EDGAR H. SCHOLLMAIER, AND LEE D. HANSEN,
Petitioners,

v.

UNITED STATES OF AMERICA,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the First Circuit

REPLY MEMORANDUM FOR ALCON LABORATORIES

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Respondent (the government) seeks to avoid review of the opinion of the court of appeals by (i) refusing to discuss the questions presented, (ii) obscuring the effect of the opinion of the First Circuit, (iii) misstating the legal principles in issue, and (iv) misrepresenting its prior positions before both the trial court and the court of appeals. Such indirection necessitates the following response:

1. The questions presented seek this Court's review of fundamental principles applicable to the labeling

and legality of thousands of drug products. The reasons why this Court should grant review have been clearly stated. (Pet. 7-10)

2. The government has, for the most part, declined to discuss the legal effect of the First Circuit's opinion—particularly with respect to the labeling of drug products marketed without express approval of the Food and Drug Administration. In so doing, the government has tacitly agreed with Petitioner's analysis of that opinion.

3. This case does not involve merely the application of settled law to given facts. The court of appeals could not have applied "settled principles to the particular facts of this case" (Br. in Opp. 5) because some of the principles involved were never discussed (Pet. 24); and, those principles which were discussed are far from being "settled." (Pet. 20) Moreover, the government's proffered guidance to this Court with respect to its opinion in *United States v. Generix Drug Corporation*, et al., 103 S. Ct. 1298 (1983) is manifestly unnecessary and inappropriate.[1]

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[1]The government presumes to further suggest that it may unilaterally determine the legality of a drug product without benefit of a judicial determination. (Br. in Opp. n.6, p.8.) Whether the product to which WANS was compared could be legally sold has never adjudicated.

The government also misstates the testimony of Alcon's expert witness. (Mem. in Op. 5). Among other things, the witness testified that there was no significant difference in the two drugs' clinical effect—the precept suggested by this Court in *Generix* and subsequently adopted by Congress in Title I of the Drug Price Competition and Patent Term Restoration Act of 1984. Pub. L. 98-417, 98 Stat. 1585.

4. The government now disingenuously urges that the teachings of *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 609 (1973) and *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973) directly support its position while having previously argued the exact opposite before the trial court and the court of appeals. (Pet. App. 99a) The government's own ambivalence belies its argument to this Court with respect to the application of "settled principles" to particular facts.

CONCLUSION

The government's refusal to address the questions presented and issues involved further confirms the merits of Alcon's petition to this Court. The petition for writ of certiorari should be granted.

Respectfully submitted,

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